Standard Operating Procedure – Breaking the Statistical Blind

This cover sheet controls the layout and components of the entire document.

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Note: This document will be issued for training at the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision as posted on the caBIG™ website.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	December 13, 2005	SOP WG Review	All pages	Document Creation
1.0	December 13, 2005	SOP WG Approval	All pages	Document Creation
1.0	January 10, 2006	BP SIG Approval	All pages	Document Creation
1.0	October 30, 2006	BP SIG/SOP WG	All pages	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the process for breaking the statistical blind during a clinical research study under the caBIG™ Program.

2. Scope

This SOP applies to the unblinding of all clinical trial research studies under the caBIG™ environment and sponsored by the National Cancer Institute (NCI) that are originally designed as blinded, randomized controlled trials. Those studies which are not blinded do not fall under the scope of this SOP.

3. Requirements

3.1 The procedures of how and why to break the statistical blind should be outlined in the protocol. All procedures taken during the unblinding process should be reported to the Clinical Study Team and thoroughly documented.

3.2 Breaking the statistical blind should be considered only when knowledge of the treatment assignment is deemed essential for the subject's care by the subject's physician or a regulatory body.

3.3 The Data Safety Monitoring Board (DSMB) or other regulatory bodies (*i.e.,* FDA, IRB) should have access to the unblinded data, when requested, for reviewing, evaluating, and/or reporting on patient safety issues or concerns during the conduct of the clinical research trial.

3.4 The blinding of clinical trial data should be maintained as per protocol requirements.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	AD-005	SOP for Protecting Patient Privacy
4.2	CR-002	SOP for Study Conduct
4.3	CR-007	SOP for Reconciliation of Serious Adverse Events

5. Roles & Responsibilities

Role	Responsibility
Principal Investigator	• Responsible for following the blind and unblinding requirements as defined by the protocol. • Should consider in advance the conditions where a blind may be broken to treat a serious adverse event, in compliance with Good Clinical Practices, 21 CFR Part 312, HHS, NIH Policy, and/or applicable ICH Guidelines, or when efficacy of the treatment regime is determined successful and the treatment should be made available to all patients in the clinical trial.
DSMB	• Responsible for reviewing, evaluating, and reporting on patient safety issues. • Able to request unblinding of clinical research data. • If unblinding is requested, the DSMB will follow their established processes for requesting unblinding of the clinical subjects.
Clinical Study Team	• Responsible for following the blind and unblinding requirements as defined by the protocol. • Execute unblinding of research subjects, when applicable (Statistician, Principal Investigator, or the Clinical Research Nurse), per established and documented standard clinical processes for clinical research trial execution.
Statistician and/or Pharmacist	• Responsible for holding the blinded randomization codes for the clinical research study.
IRB	• Responsible for the review of protocols for clinical research. • When appropriate to support their processes, can request unblinding of clinical research data for patient safety issues. • If unblinding is required, IRB will follow their established processes for requesting unblinding and/or study stop because of patient safety concerns or evidence treatment is efficacious.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all clinical research trial adopters conducting trials under the caBIG™ umbrella and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

TITLE	DESCRIPTION
1) Procedure Description for Breaking the Statistical Blind	This documents the processes for breaking the statistical blind in a clinical data management application under the caBIG™ umbrella. It provides step-by-step guidance to assure that all studies are unblinded in a consistent and controlled manner, whether for patient safety issues or treatment efficacy findings.
2) Process Flow for Breaking the Statistical Blind	This document identifies the workflow activities, by role, for the steps identified in the Procedure for Breaking the Statistical Blind.